



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,016	09/18/2006	Landon C.G. Miller	TRB-10302/38	3156
25006 7590 03/30/2010 GIFTORD, KRASS, SPRINKLE, ANDERSON & CITKOWSKI, P.C PO BOX 7021 TROY, MI 48007-7021				
EXAMINER SZMAL, BRIAN SCOTT				
ART UNIT		PAPER NUMBER		
3736				
MAIL DATE		DELIVERY MODE		
03/30/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,016

Applicant(s)

MILLER, LANDON C.G.

Examiner

Brian Szmaj

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-10 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 12, 13 and 15 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Objections

1. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 10, as currently amended, claims providing suggestions as to immediate interventional neuroprotective pharmaceutical treatments, while Claim 12 discloses providing suggestions to a user for selecting a pharmaceutical for treating the neurological injury.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim has been amended to read; "indicating the neurological injury when the detected electrical signal is beyond a preselected range of the reference value or the output signal corresponds to the presence of chemical species or concentrations indicative of the neurological injury" {emphasis added}. The current specification fails to support the "or" clause as currently claimed. The current

specification in Paragraph 0021 of the PG-Publication states the various inputs (both the neural conductivity test and the biochemical analysis) are used to provide suggestions with respect to treatment, precautions or other possible actions.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3-10, 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: The claim lacks any structural relationship between the display and the computing device and biochemical analyzer. As currently amended, the display displays only the information from the computing device; the display provides an indication of the neurological injury (provided by the processor output), and the detected electrical activity (output from the neural conductivity test). The claim fails to disclose the display providing information based upon the neural conductivity test and the biochemical analysis. For the purposes of examination, the claim is being interpreted as having three separate elements, a computing device, a biochemical analyzer and a display.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3-7, 10, 13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Sabol et al (2004/0122719 A1), as evidenced by Gozani et al (2002/0183647 A1).

Sabol et al disclose an expert system for providing a diagnosis and/or treatment options based upon a plurality of inputs, and further disclose a computing system comprising a display, in communication with: a nerve conductivity testing means, and a biochemical analyzer for analyzing fluid samples for the presence of chemical species or concentrations indicative of neurological injury; the system providing treatment suggestions; a database of neurological knowledge; a wireless transmitter coupled to the computing device communicating the indication of neurological injury and input; a user interface for data input to the computing device; an ancillary monitoring device providing the computing device with an input relating to a physiological parameter of the subject; communicating at least one of the detected electrical signal or indicated neurological injury to a remote location; and instructing the user to perform a physical examination to obtain information and providing the information to the computing device. See Figures 4 and 8; Paragraphs 0001, 0013, 0014, 0049, 0066, 0083, 0098-

0100, 0104, 0105, 0155, 0158, 0205-0207, 0235, 0236, 0248, 0249, 0254, 0286, 0319, 0330, 0405 and 0413-0416.

Sabol et al, while disclosing the use of nerve conduction tests (neural conductivity), fail to disclose the specific elements of the nerve conduction tests, such as at least one distal signal emitter attachable to a first position on the subject to emit an electrical signal generated by the device into the subject such that the electrical signal is communicated to a nerve in proximity to the first position; at least one signal detector attachable to a second position in electrical communication with a subject central nervous system on the subject to detect the electrical signal transmitted by the nerve as neural conductivity; a processor for comparing a threshold reference value with the detected electrical signal and indicating the injury when the detected electrical signal is beyond a preselected range of the reference value; the database is comprised of signal strengths of various positions and muscle groups of the subject; and the device provides a user with instruction for positioning the at least one emitter and the at least one detector on the subject.

Gozani et al disclose a means for measuring nerve responses from stimulated tissue and further disclose at least one distal signal emitter attachable to a first position on the subject to emit an electrical signal generated by the device into the subject such that the electrical signal is communicated to a nerve in proximity to the first position; at least one signal detector attachable to a second position in electrical communication with a subject central nervous system on the subject to detect the electrical signal transmitted by the nerve as neural conductivity; a processor for comparing a threshold

reference value with the detected electrical signal and indicating the injury when the detected electrical signal is beyond a preselected range of the reference value; the database is comprised of signal strengths of various positions and muscle groups of the subject; and the device provides a user with instruction for positioning the at least one emitter and the at least one detector on the subject. See Paragraphs 0002, 0004, 0031, 0036, 0037, 0039-0041, 0043, 0049, 0050 and 0053.

Since Sabol et al clearly disclose the use of nerve conduction tests, Sabol et al also disclose the specific elements of the nerve conduction testing means, as taught by Gozani et al.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 8, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabol et al (2004/0122719 A1) as evidenced by Gozani et al (2002/0183647 A1) as applied to claims 1 and 10 above, and further in view of Traynelis et al (2004/0138502 A1).

Sabol et al as evidenced by Gozani et al, as discussed above, disclose an expert system having the ability to conduct nerve conduction tests and blood analysis tests to diagnose and provide treatment suggestions based on the results of the nerve

conduction tests and the blood analysis, but fail to explicitly disclose neuroprotective pharmaceutical treatment to prevent neurological damage.

Traynelis et al disclose drug treatments including neuroprotective drugs for preventing neurological damage. See Abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Sabol et al as evidenced by Gozani et al, to include the use of neuroprotective drug treatments, as per the teachings of Traynelis et al, since it would provide a treatment means if an injury is detected by the expert system via the nerve conduction test and the blood analysis.

Allowable Subject Matter

11. Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

12. Applicant's arguments with respect to claims 1, 3-10, 12 and 13 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmaj/
Examiner, Art Unit 3736